

**REMARKS**

The pending Office Action addresses and rejects claims 1-9 and 13-27.

***Interview Summary***

Applicant thanks the Examiner for extending the courtesy of a telephone interview to Applicant's attorneys on March 31, 2008. During the Interview, Applicant's attorneys explained the differences between the Saul 915 reference which teaches an automated device for regulating cerebral spinal fluid and the claimed invention which requires manually energizing an implantable shunt system for regulating the same. Although no formal agreement was reached, the Examiner seemed inclined to allow the amended claims over the art of record.

***Amendments to the Claims***

The following claim amendments are offered solely to expedite prosecution of the present application, and do not reflect upon the patentability of the amended claim. Indeed, Applicant maintains the right to pursue any former form of a pending claim, or canceled claim, in a related continuing application.

Applicant amends independent claim 1 to specify that the method includes manually energizing the implantable shunt system with the external system controller device. Applicant similarly amends independent claim 17 to specify that the selectively operable external system controller device is configured to manually energize the implantable shunt system. Support for these amendments can be found throughout the specification, for example, at paragraph [0041]. No new matter is added.

***Rejection Pursuant to 35 U.S.C. §103*****Claims 1-4, 6, 7, 9, 13-15, and 17-26**

The Examiner rejects claims 1-4, 6, 7, 9, 13-15, and 17-26 pursuant to 35 U.S.C. §103(a) as being obvious over US 2003/0032915 A1 to Saul ("Saul 915") in view of U.S. Patent 6,533,733 to Ericson et al. ("Ericson"). The Examiner asserts that Saul 915 teaches the claimed invention except

for “an external system controller” that “communicates with the shunt and valve system remotely via telemetry.” The Examiner relies on Ericson to teach this feature, arguing that it would have been obvious to modify the device of Saul 915 in view of Ericson to arrive at the claimed invention. Applicant respectfully disagrees.

Independent claim 1, as amended, recites a method of regulating cerebrospinal fluid flow in a hydrocephalus patient that includes manually energizing an implantable shunt system with an external system controller device. Similarly, independent claim 17, as amended, recites an apparatus for regulating cerebrospinal fluid that includes a selectively operable external system controller device that is configured to manually energize an implantable shunt system of the apparatus.

A person skilled in the art would not be motivated to modify Saul 915 in view of Ericson to include a selectively operable external system controller device for manually energizing the system. In commenting on Applicant’s arguments, the Examiner asserts that because the controller taught by Saul 915 can be programmed to operate the system based on a variety of algorithms, “the controller may be programmed to await a signal from an external device” to energize the system. (Office Action, pg. 8). The mere fact that the controller may be *capable* of being programmed to await a signal from an external device to energize the system does not mean that a person skilled in the art would be motivated to make such a modification. MPEP §2143.01(V) states that “[i]f the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.” As previously explained by Applicant, the method and apparatus disclosed by Saul 915 require *continuously monitoring* a patient’s intracranial pressure and *automatically* opening or closing a valve in order to maintain a target pressure in the ventricles over a period of time. In contrast, the method and apparatus of the claimed invention require the patient or attending physician to manually energize the system using the external controller device. Energizing the system is a positively recited method step that requires the shunt system to be manually energized by an external controller *each time* the method is performed. Modifying Saul 915 to include such an external controller would render Saul 915 unsatisfactory for its intended purpose because Saul 915 could no longer continuously monitor a patient’s intracranial pressure, as the system would have to

be manually energized by an operator. The mere fact that Saul 915's controller could be modified to await a signal from an external controller does not provide the requisite motivation. Simply put, no person having ordinary skill in the art would be motivated to modify a method and device aimed at continuous, automatic operation to include the intervening step of manually energizing.

Moreover, modifying Saul 915 to include the intervening step of manually energizing would require a substantial redesign and reconstruction of the device. MPEP §2143.01 explains that, if the "suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate," then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). Modifying Saul 915 to facilitate manual energization would require removing the existing internal controller and providing Saul 915 with a selectively operable external system controller device that is configured to manually energize the system. This modification amounts to a substantial reconstruction and redesign of the Saul 915 device. Moreover, it also ignores the teachings of Saul 915 and changes the basic principle under which the Saul 915 device was designed to operate – i.e., continuous and automatic monitoring of a patient's intracranial pressure.

Even further, contrary to the Examiner's assertion, moving from an automatic activity to a manual activity is not inherently obvious. The Examiner asserts that because it has been broadly held that "providing an automatic or mechanical means to replace a manual activity which accomplished the same result is not sufficient to distinguish over the prior art," the same is true for providing a manual means to replace an automatic means. (Office Action, pg. 7) Applicant respectfully disagrees. There is simply no basis for this conclusion. As acknowledged by the Examiner, "the courts have not specifically held that such a conversion from automatic to manual activity is obvious." In fact, a person skilled in the art would likely conclude that replacing automated means with manual means would result in a system that is *inferior* to the original. Thus, such a modification is not inherently obvious.

Accordingly, independent claims 1 and 17, as well as claims 2-16 and 18-27 which depend directly or indirectly therefrom, distinguish over Saul 915 and Ericson, taken alone or combined, and represent allowable subject matter.

Claims 5, 8, 16, and 27

The Examiner rejects claims 5, 8, 16, and 27 pursuant to 35 U.S.C. §103(a) as being obvious over Ericson in view of Saul 915 and further in view of US 2003/0004495 A1 of Saul ("Saul 495"). The Examiner asserts that Ericson and Saul 915 teach the claimed invention "with the exception of repeating the resistance adjustment procedure at proscribed time intervals" and "a timed shut-off mechanism," relying on Saul 495 to teach these features. Claims 5, 8, and 16 depend from independent claim 1 and claim 27 depends from independent claim 17. As discussed above, one skilled in the art would have no motivation to combine Ericson and Saul 915, and therefore claims 5, 8, 16, and 27 are allowable at least because they depend from allowable claims 1 and 17.

***Conclusion***

In view of the above amendments and remarks, Applicant submits that all claims are in condition for allowance, and allowance thereof is respectfully requested. Applicant encourages the Examiner to telephone the undersigned in the event that such communication might expedite prosecution of this matter.

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Respectfully submitted,

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